DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS

OCT 24 2000

Mr. Martin Maxwell
President
National Home Products Ltd.
188 Limestone Crescent
Downsview, Ontario
M3J 2S4 Canada

Dear Mr. Maxwell:

During the initial inspection of your firm located in Downsview, Ontario, Canada, on August 28-29, 2000 our investigator determined that your firm manufactures sterile adhesive bandages. These products are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to ensure that quality system requirements are effectively established and effectively maintained in accordance with 21 CFR 820, as required by 21 CFR 820.20(b)(3)(i). For example, your firm has no quality system as evidenced by the lack of written procedures, quality audits, management reviews, and a quality policy.

2. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21CFR 820.198(a). For example, your firm lacks complaint handling procedures.

3. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm lacks procedures for quality audits.

4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, although the adhesive bandages are labeled as sterilized, invoices received from the supplier do not state that products are sterile, and there is no other documentation stating such.

5. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example:

   a. Your firm lacks written procedures for the analysis of quality data.
   b. Your firm lacks written procedures for the investigations of causes of nonconformities.

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, there are no procedures to address the identification, documentation, evaluation, segregation and disposition of non-conforming product.

7. Failure to establish and maintain procedures for control of labeling activities, as required by 21 CFR 820.120. For example, your firm lacks written procedures for their labeling activities, and there are no records maintained for these activities.

8. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed, as required by 21 CFR 820.150(a). For example, your firm lacks segregated areas for in-coming, in-process, quarantine, and finished product.

9. Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820, as required by 21 CFR 820.40. For example, your firm lacks procedures for the control of required documents.

10. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, acceptance procedures for inspections, tests, or other verification activities were not defined and documented.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health